

10/536782

JC13 Rec'd PCT/PTO 26 MAY 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(s): ESTEVE-SOLER, et al.

SERIAL NO.: ART UNIT:

FILING DATE: HEREWITH EXAMINER:

TITLE: USE OF 2,5-DIHYDROXYBENZENESULFONIC COMPOUNDS  
FOR THE TREATMENT OF DISORDERS BASED ON AN  
IMPARTMENT OF NO PRODUCTION AND/OR OF  
REGULATION OF EDHF FUNCTION

ATTORNEY  
DOCKET NO.: 785-012246-US (PAR)

Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT  
(37 C.F.R. §1.97(b)(2))**

Sir:

This information disclosure statement is being filed within three months of the date of entry of the national stage as set forth in §1.491 in an international application.

The following information is being disclosed to the Patent and Trademark Office as information that may be material to the examination of the above-identified patent application.

The above-identified patent application has a counter part PCT patent application No. PCT/EP2003/013469. Applicant's attorney encloses a copy of an International Search Report issued on April 29, 2004, for the counter part application. The International Search Report cites several references, listed below, that are being disclosed to the Patent and Trademark Office as information

that may be material to the examination of the above-identified patent application.

US 6,290,990 B1

US 4,871,742

DE 100 16 356 A1

FR 2 656 525

WO 97/37647

"Effects of calcium dobesilate on the synthesis of endothelium-dependent relaxing factors in rabbit isolated aorta", E. Ruiz, et al., British Journal of Pharmacology (1997) 121, 711-716

"Calciumdobesilat", Aus Anderen Zeitschriften, 292-293

"Calcium Dobesilate in Diabetic Retinopathy - A Retrospective Controlled Study", Christian Adank, et al., Ophthalmologica, Basel 190:102-111 (1985)

"Diabetes Mellitus", Nephrology Dialysis Transplantation, Vol. 16, N.6, 2001, A78

"Calcium Dobesilate: Pharmacology and Future Approaches", T.Tejerina, et al., Gen. Pharmac. Vol. 31, No. 3, pp.357-360, 1998

"Clinical trials of calcium dobesitate in diabetic retinopathy", Temprano Acedo J., EMBASE/Elsevier, 1973, Vol. 11, pages 9-16

"Calcium dobesilate potentiates endothelium-derived hyperpolarizing factor-mediated relaxation of human penile resistance arteries", Javier Angulo, et al., British Journal of Pharmacology (2003) 139, 854-862

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"Il Dobesilato Di Calcio Nel Trattamento Di Soggetti Con Microangiopatia Diabetica", M. Guerrini, et al., La Riforma Medica, Vol. 103, N. 1-2, 7-12

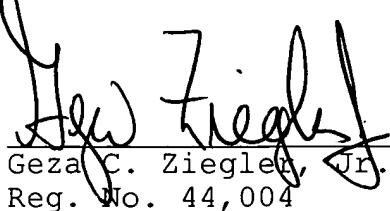
"Diabetes impairs endothelium-dependent relaxation of human penile vascular tissues mediated by NO and EDHF", Javier Angulo, et al., Biochemical and Biophysical Research Communications 312 (2003) 1202-1208

"Calcium Dobesilate: Pharmacological Profile Related to its Use in Diabetic Retinopathy", P. Berthet, et al., IJCP, December 1999 Vol. 53, No. 8, 631-636

Copies of these references are enclosed together with a Form PTO-1449 for the Examiner's use.

The filing of this Statement is not to be construed as a representation that a search has been made regarding the claimed invention (37 C.F.R. §1.97(g)) or that no other possible material information exists. In addition, the filing of this Information Disclosure Statement is not to be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability (37 C.F.R. §1.97(h)).

Respectfully submitted,

  
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26 May 2005  
Date

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| <b>INFORMATION DISCLOSURE<br/>CITATION FORM FOR<br/>PATENT APPLICATION<br/>(FORM PTO-1449)<br/>(Substitute)</b>   |   | Docket No.: 785-012246-US (PAR)    |                                  | Serial No.:   |            |                            |
|---|---|------------------------------------|----------------------------------|---|------------|----------------------------|
|   |   | Applicant(s): ESTEVE-SOLER, et al. |                                  |   |            |                            |
|   |   | Filing Date: Herewith              | Group:                           |   |            |                            |
| <b>U.S. PATENTS</b>   |   |                                    |                                  |   |            |                            |
| Initials  | Patent Number                                   | Issue Date                         | Name                             | Class   | Sub-class  | Filing date                |
|   | 6,290,990<br>4,871,742                          | 9/18/01<br>10/3/89                 | Grabowski et al.<br>Bonne et al. | 424<br>514  | 499<br>262 | 4/15/95<br>12/4/87         |
| <b>U.S. PATENT PUBLICATIONS</b>   |   |                                    |                                  |   |            |                            |
| Initials  | Publication No.                                 | Pub. Date                          | Name                             | Class   | Sub-class  | Filing Date                |
|   |   |                                    |                                  |   |            |                            |
| <b>FOREIGN PATENT DOCUMENTS</b>   |   |                                    |                                  |   |            |                            |
| Initials  | Document Number                                 | Date                               | Country                          | Name  |            | Translation?<br>Yes/No/n/a |
|   | DE 100 16 356 A1<br>FR 2 656 525<br>WO 97/37647 | 10/4/01<br>7/5/91<br>10/16/97      | Germany<br>France<br>PCT         | Beisel, Gunther<br>Delalande (S.A.)<br>Laboratorios Del Dr.<br>Esteve, S.A. |            | No<br>No<br>No             |
| <b>OTHER DOCUMENTS (Title, Author, Date, Pages, Etc., if known)</b>   |   |                                    |                                  |   |            |                            |
| "Effects of calcium dobesilate on the synthesis of endothelium-dependent relaxing factors in rabbit isolated aorta", E. Ruiz, et al., British Journal of Pharmacology (1997) 121, 711-716                                     |   |                                    |                                  |   |            |                            |
| "Calciumdobesilat", Aus Anderen Zeitschriften, 292-293  |   |                                    |                                  |   |            |                            |
| "Calcium Dobesilate in Diabetic Retinopathy – A Retrospective Controlled Study", Christian Adank, et al., Ophthalmologica, Basel 190:102-111 (1985)   |   |                                    |                                  |   |            |                            |
| "Diabetes Mellitus", Nephrology Dialysis Transplantation, Vol. 16, N.6, 2001, A78   |   |                                    |                                  |   |            |                            |
| "Calcium Dobesilate: Pharmacology and Future Approaches", T. Tejerina, et al., Gen. Pharmac. Vol. 31, No. 3, pp.357-360, 1998   |   |                                    |                                  |   |            |                            |
| "Clinical trials of calcium dobesitate in diabetic retinopathy", Temprano Acedo J., EMBASE/Elsevier, 1973, Vol. 11, pages 9-16  |   |                                    |                                  |   |            |                            |
| "Calcium dobesilate potentiates endothelium-derived hyperpolarizing factor-mediated relaxation of human penile resistance arteries", Javier Angulo, et al., British Journal of Pharmacology (2003) 139, 854-862               |   |                                    |                                  |   |            |                            |
| "Il Dobesilato Di Calcio Nel Trattamento Di Soggetti Con Microangiopatia Diabetica", M. Guerrini, et al., La Riforma Medica, Vol. 103, N. 1-2, 7-12   |   |                                    |                                  |   |            |                            |
| "Diabetes impairs endothelium-dependent relaxation of human penile vascular tissues mediated by NO and EDHF", Javier Angulo, et al., Biochemical and Biophysical Research Communications 312 (2003) 1202-1208                 |   |                                    |                                  |   |            |                            |
| "Calcium Dobesilate: Pharmacological Profile Related to its Use in Diabetic Retinopathy", P. Berthet, et al., IJCP, December 1999 Vol. 53, No. 8, 631-636   |   |                                    |                                  |   |            |                            |
| Examiner's Signature:   |   |                                    |                                  | Date Considered:  |            |                            |
| Initial if reference was considered, whether or not citation is in conformance with MPEP. Mark through citation if not considered.<br>Include a copy of this citation form with your next correspondence to the Applicant(s). |   |                                    |                                  |   |            |                            |